CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2005 –12/31/2005

(Sorted by date)

Title	Subject	Level at Date of Issue	Publication/ Withdrawal Date	Status
Labeling Over-the-Counter Human Drug Products; Questions and Answers	OTC Draft	Level 1	1/13/2005	New
Nonclinical Safety Evaluation of Drug Combinations	Pharmacology Toxicology Draft	Level 1	1/26/2005	New
Abbreviated New Drug Applications: Impurities in Drug Substances; Chemistry, Manufacturing, and Controls Information	Chemistry Draft	Level 1	1/31/2005	New
S8 Immunotoxicity Studies for Human Pharmaceuticals	ICH Safety Draft	Level 1	2/8/2005	New
Clinical Lactation Studies-Study Design, Data Analysis, and Recommendations for Labeling	Clinical Medical Draft	Level 1	2/8/2005	New
Q8 Pharmaceutical Development	ICH Quality Draft	Level 1	2/9/2005	New
Internal Radioactive Contamination-Development of Decorporation Agents	Clinical Medical Draft	Level 1	2/15/2005	New
E2B(M) Questions and Answers	ICH Efficacy	Level 2	3/9/2005	Revised
M2: eCTD Specification Questions and Answers and Change Requests	Joint Safety/Efficacy	Level 2	3/14/2005	New
Centralized IRB Review Proceedings in Multicenter Clinical Trials	Procedural Draft	Level 1	3/28/2005	New

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Systemic Lupus Erythematosus-Developing Drugs for Treatment	Clinical Medical Draft	Level 1	3/29/2005	New
Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics	Clinical Medical Draft	Level 1	4/4/2005	New
Exploratory IND Studies	Pharmacology Toxicology Draft	Level 1	4/14/2005	New
User Fee Waivers for Fixed Dose Combination Products and Co-Packaged Human Immunodeficiency Virus Drugs for the President's Emergency Plan for Acquired Immunodeficiency Syndrome Relief	User Fee Draft	Level 1	4/18/2005	New
FDA's "Drug Watch" for Emerging Drug Safety Information	Drug Safety Draft	Level 1	5/10/2005	New
Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients	Pharmacology Toxicology	Level 1	5/19/2005	New
Antiviral Drug Development Conducting Virology Studies and Submitting the Data to the Agency	Clinical/Antimicrobial Draft	Level 1	5/25/2005	New
Useful Written Consumer Medication Information (CMI)	Procedural Draft	Level 1	5/26/2005	New
Expiration Dating of Unit-Dose Repackaged Drugs: Compliance Policy Guide	Compliance Draft	Level 1	5/31/2005	Revised
Safety Testing of Drug Metabolites	Pharmacology Toxicology Draft	Level 1	6/6/2005	New

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Bar Code Label Requirements – Questions and Answers	Compliance Draft	Level 1	6/7/2005	New
Clozapine Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing	Biopharmaceutics	Level 1	6/20/2005	Revised
Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals	Pharmacology Toxicology Draft	Level 1	6/20/2005	New
Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention	Clinical/Medical Draft	Level 1	6/28/2005	New
Q5E: Comparability of Biotechnological/Biological Products subject to Changes in Their Manufacturing Process	ICH Quality	Level 2	6/30/2005	New
Emergency Use Authorization of Medical Products	Procedural Draft	Level 1	7/5/2005	New
Preclinical Development of Antiviral Drugs	Clinical/Antimicrobial	Level 1	7/6/2005	Withdrawn
Companion Document for M2: eCTD Specification Questions & Answers and Change Requests	ICH Joint Safety/Efficacy (Multidisciplinary)	Level 2	7/18/2005	New
Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers	Pharmacology Toxicology	Level 1	7/22/2005	New
Q9: Quality Risk Management	ICH Quality Draft	Level 2	8/8/2005	New
Conjugated Estrogens, USP: LC-MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence	Biopharmaceutics Draft	Level 1	8/12/2005	Withdrawn

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ANDAs: Impurities in Drug Products	Generics Draft	Level 1	8/29/2005	Revised
M5: Data Elements and Standards for Drug Dictionaries	ICH Draft	Level 2	9/6/2005	New
Phenytoin/Phenytoin Sodium Capsules, Tablets and Suspension *In Vivo* Bioequivalence and *In Vitro* Dissolution Testing	Biopharmaceutics	Level 1	9/6/2005	Withdrawn
How to Comply with the Pediatric Research Equity Act	Procedural Draft	Level 1	9/7/2005	New
Acne Vulgaris: Developing Drugs for Treatment	Clinical/Medical Draft	Level 1	9/19/2005	New
Collection for Race and Ethnicity Data in Clinical Trials	Clinical/Medical	Level 1	9/19/2005	New
Current Good Manufacturing Practice for Positron Emission Tomography Drug Products	Compliance Draft	Level 1	9/20/2005	New
E2B(R): Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports	ICH Draft	Level 1	10/3/2005	New
M4: Common Technical Document for the Registration of Pharmaceuticals for Human Use – Granularity Annex	ICH	Level 4	10/17/2005	New
Providing Regulatory Submission in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the Electronic Common Technical Document	Electronic Submissions	Level 1	10/19/2005	New
E14: Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs	ICH	Level 4	10/20/2005	New

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S7B: Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals	ICH	Level 4	10/20/2005	New
Potassium Chloride Modified-release Tablets and Capsules: *In Vivo* Bioequivalence and *In Vitro* Dissolution Testing	Generics	Level 1	10/26/2005	New
Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms — Recommended Prescribing Information for Health Care Providers and Patient Labeling	Labeling Draft	Level 1	11/16/2005	Revision
Organization of an Abbreviated New Drug Application	Generics	Level 2	11/18/2005	Withdrawn
SPL Standard for Content of Labeling Technical Qs & As	Electronic Submissions	Level 2	12/8/2005	New
Preclinical Development of Immunomodulatory Drugs for Treatment of HIV Infection and Associated Disorders	Clinical Medical	Level 1	12/29/2005	Withdrawn